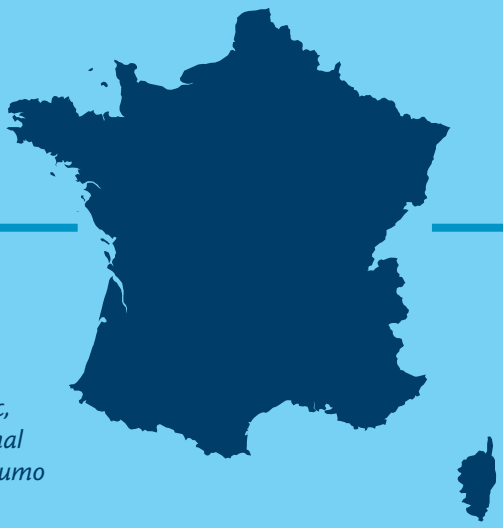
# France



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## What is the prevalence of endovascular SFA therapy as compared to surgical?

In France, endovascular SFA therapy is rising for different reasons. Currently, vascular surgeons perform 85% of procedures, 10% are performed by cardiologists, and 5% are performed by radiologists. Almost all young French vascular surgeons are trained to perform peripheral and aortic endovascular procedures. Also, indications for SFA therapy have evolved. In the past, SFA therapy was indicated for very severe claudication or, for some centers, only in the case of critical limb ischemia (CLI). Patient quality of life is greatly affected by disabling claudication and is now taken into account. Thirdly, recent advances in endovascular techniques have led to widespread endovascular repair for more severe femoropopliteal lesions. Although lesions are longer and more distal, the technical success rates and clinical results are promising. Consequently, this has led to expanded indications and the treatment of longer SFA lesions. Finally, the use of new techniques and devices, such as a retrograde approach and reentry catheters, have improved the technical success rates after failed initial procedures.

## How would you describe device availability in your country, both in types of devices and different vendors within each class?

In France, almost all companies are present and most of those dedicated to the treatment of peripheral artery disease (PAD) work directly with the French market without any distributors. All CE Mark–approved devices can be used; however, they may or may not be reimbursed. For PAD, implantable devices are reimbursed (ie, mostly covered stents, bare-metal stents [BMS], and drug-eluting stents [DES]). Balloon catheters, guidewires, sheaths, crossing catheters, as well as drug-coated balloons (DCBs) and debulking devices do not get reimbursed. Thus, the devices' cost must be covered by the diagnosis-related group (DRG) funds. Consequently, device cost should be balanced with the efficiency and clinical results of the device, and the choice depends on a discussion between physicians, pharmacists, and/or the private hospital and the device company. Because the most expensive devices (debulking devices, DCBs) do not get reimbursed, they are not routinely used. Device availability also varies by device company. In some cases, a device company is not able to provide clinical or medicoeconomic data to apply for reimbursement. In other cases, a device in a particular class could be recommended, but the cost, which is determined by the government commission, precludes the device from use. Consequently, the device is not promoted for use in the French market.

## In what ways does reimbursement (both government and private if applicable) affect device use? Which device classes are most affected?

Device use is driven by reimbursement. Right now, only implanted devices are reimbursed. To apply for a device reimbursement, a company submits a dossier to the Commission nationale d'évaluation des dispositifs médicaux (CNEDiMTS). When a device is approved by the CNEDiMTS, the Commission d'évaluation des produits et des prestations (CEPP) then determines the reimbursement price. The dossier's quality (clinical and medicoeconomic data) is crucial to obtain the reimbursement and a reasonable cost. Currently, stents and covered stents are not included in the DRG and require a separate reimbursement. Each year, the price of this reimbursement is decreasing. A class effect is recognized for peripheral BMS (balloon- and self-expandable stents). Recently, French vascular interventionists have experienced difficulties using DCBs because they are considered a nonimplantable device, and reimbursement is not provided. Efforts from French authorities are ongoing to account for this type of innovation (ie, nonimplantable) and give physicians the opportunity to assess such innovative devices. Currently, some university hospitals have the opportunity to get grants from their institution to use nonreimbursed devices for 1 to 2 years.

### Are there any historic or cultural forces unique to your country that have affected the penetration of endovascular options?

Fifteen years ago, radiologists were leading the endovascular market. Sixty percent, 35%, and 5% of procedures were performed by radiologists, vascular surgeons, and cardiologists, respectively. During the 1990s, some vascular surgeons in the French Society of Vascular Surgery were pioneers in endovascular therapies. Despite some resistance, public and private French vascular surgeons embraced the endovascular approach, and now 85% of endovascular procedures are performed by vascular surgeons, 10% are performed by cardiologists, and 5% are performed by radiologists. Compared to other countries, angiologists do not perform arterial endovascular procedures and instead mostly perform duplex scanning and venous interventions.

### How do most physicians receive training in endovascular therapies in your country?

First, training is given during the vascular surgery fellowship. All fellows in French university hospitals receive endovascular training for aortic and peripheral therapies. Moreover, use of endovascular therapies is still growing in academic centers, which allows for extensive education for fellows. After the fellowship period, vascular surgeons are trained in different ways. Of course, medical conferences give an extensive knowledge of new techniques or trial results, but in many cases, it is difficult for the physicians to ask questions to key opinion leaders. For French physicians, language can be a barrier to discussion, and also the medical conference format does not allow a discussion between the panel and the floor. Workshops or small medical conferences are a more direct and simple way to share information with colleagues and are more appreciated for particular topics or techniques. In most cases, industry is the main financial support for education, although recently, the French government has provided government funding for medical education.

### What is your personal strategy or algorithm for treating the various lesion types?

Endovascular therapy is the first line of treatment for all femoropopliteal lesions, including for claudication, CLI, and long and complex lesions. The first issue, mostly in the case of thrombosis, is the level of reentry. For patients with claudication, we limit the level of the reentry at P2 (included). In the setting of CLI, we do not have a limit for the reentry level. Not all devices are well evaluated, and others have shown superiority versus plain old balloon angioplasty (POBA). Consequently, we cannot draw a robust treatment algorithm due to lack of evidence. Nevertheless, among factors that we have to take into consideration, the type of lesion (de novo or restenosis) is crucial. For in-stent restenosis (< 2 years from stent implantation), DCB seems to be the best strategy considering the prevalence of intimal hyperplasia. However, in the case of restenosis after POBA, the role of early recoil or a late constrictive remodeling should be considered and thus a DES could be the best option. The algorithm appears to be more challenging for de novo lesions. Criteria such as patient clinical status (claudication versus CLI), lesion length, and technique of recanalization (intra versus subintimal) should be taken into consideration to treat de novo femoropopliteal lesions. In our experience, for shorter lesions (< 2 cm), POBA is performed. For longer lesions (≤ 15 cm), BMS is still implanted given the lack of studies comparing BMS, DCB, and DES, as well as the French market constraints. For lesions > 15 cm, which are often more complicated (occlusions, calcifications), results have been promising with BMS. Studies comparing these devices are ongoing and will help us to more precisely define our strategy for SFA endovascular therapy. ■